General

Guideline Title

An international ISHLT/ATS/ERS clinical practice guideline: diagnosis and management of bronchiolitis obliterans syndrome.

Bibliographic Source(s)

Meyer KC, Raghu G, Verleden GM, Corris PA, Aurora P, Wilson KC, Brozek J, Glanville AR, ISHLT/ATS/ERS BOS Task Force Committee. An international ISHLT/ATS/ERS clinical practice guideline: diagnosis and management of bronchiolitis obliterans syndrome. Eur Respir J. 2014 Dec;44(6):1479-503. [180 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The strength of the recommendations (strong, conditional) and quality of evidence (high, moderate, low or very low) are defined at the end of the "Major Recommendations" field.

Risk Factors Associated with the Development of Bronchiolitis Obliterans Syndrome (BOS)

Non-minimal (Grade ≥A2) Acute Cellular Rejection and Lymphocytic Bronchiolitis

Recommendation 1

For lung transplant recipients who have non-minimal acute cellular rejection (Grade ≥A2) or lymphocytic bronchiolitis on transbronchial lung biopsy specimens, the Committee suggests augmented immunosuppression with a course of systemic steroids to prevent the development of BOS (conditional recommendation, very low quality evidence).

Values and Preferences

This recommendation places a high value on preventing a life-threatening complication of lung transplantation and a lower value on avoiding short-term adverse effects.

Remarks

A typical course of systemic corticosteroids used to augment immunosuppression in adult recipients is intravenous methylprednisolone 1000 mg

daily for 3 days (many centres use 10-15 $mg \cdot kg^{-1}$ per day for smaller patients).

Minimal (Grade A1) Acute Cellular Rejection

Recommendation 2

For lung transplant recipients who have clinically significant minimal acute cellular rejection (Grade A1) on transbronchial lung biopsy specimens, the Committee suggests augmented immunosuppression with a course of systemic steroids to prevent the development of BOS (conditional recommendation, very low quality evidence).

Values and Preferences

This recommendation places a high value on preventing a life-threatening complication of lung transplantation and a lower value on avoiding short-term side-effects.

Remarks

The Committee members consider Grade A1 acute cellular rejection to be clinically significant if it is associated with clinical findings, such as symptoms (e.g., dyspnoea, fatigue or new-onset cough) or objective measurements (e.g., decline in forced expiratory volume in 1 second [FEV_1] or oxyhaemoglobin desaturation with ambulation), that suggest the presence of allograft dysfunction. A typical course of systemic steroids used to augment immunosuppression in adult recipients is intravenous methylprednisolone 1000 mg daily for 3 days (many centres use 10–15 $mg \cdot kg^{-1}$ per day for smaller patients).

Treatment and Prevention of BOS

Long-Term High-Dose Corticosteroids

Recommendation 3

For lung transplant recipients who develop a decline in FEV_1 consistent with the onset of BOS, the Committee suggests that clinicians do not use long-term, high-dose corticosteroids (conditional recommendation, very low quality evidence).

Values and Preferences

This recommendation places a high value on avoiding harmful effects due to ineffective therapies.

Remarks

The Committee defines sustained administration of high-dose corticosteroid as ≥ 30 $mg \cdot day^{-1}$ of prednisone or an equivalent formulation.

Converting Cyclosporine to Tacrolimus

Recommendation 4

For lung transplant recipients who develop BOS while receiving chronic immunosuppression with a regimen that includes cyclosporine, the Committee suggests switching the cyclosporine to tacrolimus (conditional recommendation, very low quality evidence).

Values and Preferences

This recommendation places a higher value on mitigation of lung function decline and a lower value on avoiding nephrotoxicity and hyperglycaemia.

Remarks

The conversion of cyclosporine to tacrolimus is generally performed by stopping cyclosporine and initiating tacrolimus while transiently increasing maintenance corticosteroid dosing until tacrolimus blood levels are ascertained to have reached the desired target range. The target for therapeutic trough blood levels of tacrolimus is generally considered to range from 5 to 15 $ng \cdot mL^{-1}$ for patients who are ≥ 18 years of age once a steady state has been attained.

Azithromycin

Recommendation 5

For lung transplant recipients who develop a decline in FEV_1 consistent with the onset of BOS, the Committee suggests a trial of azithromycin (conditional recommendation, very low quality evidence).

Values and Preferences

This recommendation places a high value on preventing lung function deterioration and possibly reducing mortality, and a lower value on avoiding adverse effects.

Remarks

Azithromycin is generally administered orally at 250 mg per day for 5 days and then 250 mg three times per week. The Committee defines a trial of azithromycin as treating continuously with azithromycin for a minimum of 3 months. Additionally, it is unclear 1) whether azithromycin should be continued long-term if a beneficial response is observed, or 2) whether it should be discontinued if lung function does not show improvement during follow-up clinical evaluation.

Anti-reflux Surgery

Recommendation 6

For lung transplant recipients who develop a decline in FEV_1 consistent with the onset of BOS and have confirmed gastro-oesophageal reflux (GOR), the Committee suggests referral to an experienced surgeon to be evaluated for potential fundoplication of the gastro-oesophageal junction (conditional recommendation, very low quality evidence).

Values and Preferences

This recommendation places a high value on reducing the risk of lung function deterioration and possibly mortality, and a lower value on avoiding surgical complications.

Remarks

Nissen fundoplication has been more extensively studied than Toupet fundoplication; however, the Committee has no reason to believe that one is superior to the other and feels that the choice of the surgical technique should remain at the surgeon's discretion.

Re-transplantation

Recommendation 7

For lung transplant recipients who have developed end-stage BOS refractory to other therapies, the Committee suggests referral to a transplant surgeon to be evaluated for re-transplantation (conditional recommendation, very low quality evidence).

Values and Preferences

This recommendation places a high value on avoiding surgical complications (e.g., mortality), recurrent BOS and resource utilisation.

Remarks

The selection process for re-transplantation is the same as that used for first-time lung transplantation.

Definitions:

Quality of Evidence

High	Evidence includes well-designed, well-conducted randomised trials or meta-analyses of randomised trials, without risk of bias, indirectness, imprecision, inconsistency or publication bias. Alternatively, the evidence may include well-designed, well-conducted observational studies with either a very large effect or at least two of the following: a large effect, dose–response gradient, and/or reverse confounding.
Moderate	Evidence includes randomised trials or meta-analyses of randomised trials downgraded because of a serious risk of bias, indirectness, imprecision, inconsistency or publication bias. Alternatively, the evidence may include well-designed, well-conducted observational studies upgraded because of a large effect, dose–response gradient or reverse confounding.
Low	Evidence includes well-designed, well-conducted observational studies, or randomised trials or meta-analyses of randomised trials downgraded two levels because of very serious risk of bias, indirectness, imprecision, inconsistency or publication bias.

Very low	Evidence consists of case reports, case series or unsystematic clinical observations (i.e., clinical experience or expert opinion).

Strength of Recommendations

Strong	The committee feels certain that the benefits of the intervention substantially outweigh its risks, burdens and costs.
Conditional	The committee believes, but is uncertain, that the benefits of the intervention substantially outweigh its risks, burdens and costs.

Clinical Algorithm(s)

An algorithm titled "Algorithm for Clinical Evaluation of Suspected Bronchiolitis Obliterans Syndrome (BOS)" is provided in the original guideline document.

Scope

Disease/Condition(s)

- Lung transplantation
- Bronchiolitis obliterans syndrome (BOS)

Guideline Category

Management

Prevention

Treatment

Clinical Specialty

Allergy and Immunology

Critical Care

Family Practice

Internal Medicine

Pediatrics

Preventive Medicine

Pulmonary Medicine

Thoracic Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Respiratory Care Practitioners

Guideline Objective(s)

To revise the definition of bronchiolitis obliterans syndrome (BOS), discuss the risk factors for the development of BOS, and provide guidance about the management of patients with suspected or confirmed BOS

Target Population

Adults and children who have received lung transplants

Interventions and Practices Considered

1. Augmented immunosuppression with a course of systemic steroids to prevent bronchiolitis obliterans syndrome (BOS)
2. Use of long-term high-dose corticosteroids (not recommended)
3. Switching from cyclosporine to tacrolimus
4. Trial of azithromycin
5. Anti-reflux surgery
6. Re-transplantation

Major Outcomes Considered

- Risk of developing bronchiolitis obliterans syndrome (BOS)
- Freedom from BOS
- Lung function (change in forced expiratory volume in 1 second [FEV_1])
- Mortality
- Survival rates during re-transplantation
- Perioperative and postoperative complications and death
- Adverse events of treatment

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A comprehensive literature search was performed by a medical librarian. The PubMed interface was used to search MEDLINE for relevant publications (original articles and systematic reviews) from 1980 through to 2009. The search was updated twice in 2012 and in March 2013. The search was limited to humans and English language. The search terms included "lung transplantation", "bronchiolitis obliterans syndrome" and terms specific to management options considered in the clinical questions. A total of 10,031 manuscripts were identified using the electronic searches. Relevant publications were selected by committee members using pre-specified inclusion criteria, and the bibliographies of selected articles were reviewed to identify additional articles.

The Committee members used RefWorks to perform the comprehensive review, selected manuscripts that were pertinent to the review, and

created folders pertaining to bronchiolitis obliterans syndrome (BOS) diagnosis, etiology, prevention, and treatment. These manuscripts were then evaluated on a more exhaustive set of criteria per the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for quality of evidence (Committee members were assigned to subcommittees for each specific BOS subtopic and one member was selected to chair the committee and prepare reviews with supporting literature/citations) if they could be used to formulate/support guideline recommendations.

Number of Source Documents

A total of 10,031 manuscripts were identified using the electronic searches. Relevant publications were selected by committee members using pre-specified inclusion criteria, and the bibliographies of selected articles were reviewed to identify additional articles.

Number of studies pertinent to the questions and used in developing recommendations*:

- Question: Does augmented immunosuppression in patients with non-minimal acute cellular rejection (AR) (Grade ≥2) or lymphocytic bronchiolitis (LB) on transbronchial lung biopsy decrease the subsequent development of bronchiolitis obliterans syndrome (BOS)? – 11 studies.
- Question: Does augmented immunosuppression in patients with non-minimal AR (Grade ≥2) or LB on transbronchial lung biopsy decrease the subsequent development of BOS? – 9 studies.
- Question: Should sustained treatment with high-dose corticosteroids be given to lung transplant recipients who develop BOS? – 5 studies.
- Question: Does the replacement of cyclosporine with tacrolimus in the post-transplant immunosuppressive regimen slow the rate of lung function decline in patients who have developed criteria for BOS? – 10 studies.
- Question: Should azithromycin be given to patients who develop BOS? – 11 studies.
- Question: Should anti-reflux surgery (e.g., fundoplication) be performed for patients who develop BOS and have documented gastro-oesophageal reflux (GOR)? – 10 studies.
- Question: Should lung re-transplantation be offered to patients who develop end-stage BOS refractory to other therapies? – 7 studies.

*Note: Other literature was also used/cited in discussing existent knowledge/data and drawing conclusions that were not presented as recommendations.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence

High	Evidence includes well-designed, well-conducted randomised trials or meta-analyses of randomised trials, without risk of bias, indirectness, imprecision, inconsistency or publication bias. Alternatively, the evidence may include well-designed, well-conducted observational studies with either a very large effect or at least two of the following: a large effect, dose–response gradient, and/or reverse confounding.
Moderate	Evidence includes randomised trials or meta-analyses of randomised trials downgraded because of a serious risk of bias, indirectness, imprecision, inconsistency or publication bias. Alternatively, the evidence may include well-designed, well-conducted observational studies upgraded because of a large effect, dose–response gradient or reverse confounding.
Low	Evidence includes well-designed, well-conducted observational studies, or randomised trials or meta-analyses of randomised trials downgraded two levels because of very serious risk of bias, indirectness, imprecision, inconsistency or publication bias.
Very low	Evidence consists of case reports, case series or unsystematic clinical observations (i.e., clinical experience or expert opinion).

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Members of the committee were provided with the entire collection of compiled documents and subcommittees were formed to address specific topics. Each subcommittee reviewed, appraised and summarised the relevant evidence. The GRADE (Grading of Recommendation, Assessment, Development and Evaluation) approach was used to appraise the quality of the body of evidence supporting each recommendation.

The pragmatic evidence synthesis was primarily qualitative, rather than quantitative (i.e., few data could be pooled via meta-analysis).

The methods used for this guideline are summarised in Table 5 in the original guideline document.

Evidence tables summarising the relevant literature for each recommendation are provided in the online supplementary material (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

An International Society for Heart and Lung Transplantation (ISHLT), American Thoracic Society (ATS) and European Respiratory Society (ERS) sponsored *ad hoc* committee held preliminary meetings in April and May of 2008 to begin the process of identifying and prioritising topics to be covered in this guideline. The chairs were approved by the three societies. Panel members were identified as leaders in the field of lung transplantation and were selected from established transplant centres worldwide, by the chairs, to review the existing literature and to answer clinical questions based upon the published evidence or, when such evidence was lacking, to provide guidance based upon the observations in their clinical practice. Each member of the committee was involved in developing the conclusions and recommendations provided by this document.

Members of the committee were provided with the entire collection of compiled documents and subcommittees were formed to address specific topics. Each subcommittee reviewed, appraised and summarised the relevant evidence. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was used to appraise the quality of the body of evidence supporting each recommendation. Clinical questions related to treatment versus no treatment, one treatment versus an alternative treatment, or which populations to treat were answered with recommendations that were formulated and graded using the GRADE approach (see the "Rating Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations" fields). Disagreements were resolved by discussion and consensus. The final recommendations and grades were reviewed by the entire committee and approved in September 2013. In contrast to the systematically developed recommendations, other committee conclusions were based upon the literature appraisal and committee deliberations.

A strong recommendation was made if the committee felt confident of the balance between desirable and undesirable consequences. A conditional recommendation was made if the committee felt less confident of the balance between desirable and undesirable consequences. Factors that influence the strength of recommendations include the estimates of effect for desirable and undesirable outcomes of interest, confidence in these estimates of effects, estimates of values and preferences, and resource use. In any case the appropriate course of action depends upon the clinical context. The committees' judgments about the underlying values and preferences of well-informed patients were based upon the committee members' clinical experience. Evidence tables summarising the relevant literature for each recommendation are provided in the online supplementary material (see the "Availability of Companion Documents" field).

The committee identified very few experimental studies of the management of bronchiolitis obliterans syndrome (BOS). Available data are very limited owing to the small number of subjects. Thus, most of the recommendations are based upon observational studies with or without a control group and the clinical experience of the committee members (i.e., unsystematic clinical observations from their clinical practices).

Rating Scheme for the Strength of the Recommendations

Strength of Recommendations

Strong	The committee feels certain that the benefits of the intervention substantially outweigh its risks, burdens and costs.
Conditional	The committee believes, but is uncertain, that the benefits of the intervention substantially outweigh its risks, burdens and costs.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

The final recommendations and grades were reviewed by the entire Task Force Committee and approved in September 2013.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Most of the recommendations are based upon observational studies with or without a control group and the clinical experience of the committee members (i.e., unsystematic clinical observations from their clinical practices).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

This guideline is intended to enhance the understanding of the diagnosis and management of bronchiolitis obliterans syndrome (BOS) by transplant physicians and other clinicians, and to assist them in the making appropriate clinical decisions when evaluating patients in whom a diagnosis of BOS is suspected. This guideline can be used worldwide to help standardise the management of BOS. It is hoped that this guideline will provoke and facilitate future clinical studies in lung transplant recipients who develop delayed loss of allograft function.

Potential Harms

- When deciding whether or not augmented immunosuppression is warranted, the likelihood of preventing bronchiolitis obliterans syndrome (BOS) must be balanced against the harms of the increased immunosuppression. This balance will vary depending upon the regimen chosen; however, a short course of systemic steroids is the most common regimen selected. The best evidence regarding the potential adverse effects of a short course of systemic steroids is indirect, extrapolated from randomised trials conducted in patients having an exacerbation of chronic obstructive pulmonary disease (COPD). Such trials have found that short courses of systemic steroids increase the incidence of adverse effects, particularly hyperglycaemia and weight gain.
- Sustained high-dose corticosteroids increase the incidence of osteoporotic fractures, cataracts and dyspepsia.
- The most common adverse effects of azithromycin are nausea, diarrhoea, dyspepsia and colitis, occurring in fewer than 5% of patients. A meta-analysis of 12 randomised trials with 1406 patients who received azithromycin to treat an acute lower respiratory tract infection found that 244 (17.9%) out of 1363 patients developed an adverse event. Most of the adverse events were minor nausea and diarrhoea. In an observational study that looked at more than one million instances of taking azithromycin, patients who took azithromycin were more likely to suffer a fatal cardiac arrhythmia than those who did not take an antibiotic (risk ratio 2.85, 95% confidence interval [CI] 1.13–7.24). The absolute risk of a fatal cardiac arrhythmia during azithromycin therapy was small (1.1 cases per 1000 person-years) and the risk was not increased compared with patients who took an alternative antibiotic (risk ratio 0.93, 95% CI 0.56–1.55). These findings were supported by another study conducted by the maker of azithromycin. There is also evidence from a randomised trial that patients with COPD who are treated with chronic azithromycin therapy are more likely to experience a decrement in hearing and colonisation with azithromycin-resistant organisms.

- Several studies reported a complication rate of less than 5% of patients after anti-reflux surgery, a perioperative mortality rate of less than 1%, and post-operative dysphagia in 6% to 14% of patients.
- Most of the case series that described the effects of converting cyclosporine to tacrolimus in lung transplant patients with BOS did not mention adverse effects; however, those that evaluated nephrotoxicity or hyperglycaemia reported a frequent rise in the serum creatinine and glucose levels.
- The safety of re-transplantation has not been well studied. In one study, there were 39 (10%) deaths within 180 days among the 389 patients who underwent re-transplantation. The causes of death were infection, respiratory failure and multi-organ system failure. Patients undergoing re-transplantation had an increased risk for death after the procedure compared with patients who underwent primary transplantation.

Refer to the original guideline document for additional information on treatment safety.

Qualifying Statements

Qualifying Statements

The International Society for Heart and Lung Transplantation (ISHLT)/American Thoracic Society (ATS)/European Respiratory Society (ERS) guidelines about the management of bronchiolitis obliterans syndrome (BOS) are not intended to impose a standard of care. They provide the basis for rational decisions in the management of patients with suspected or confirmed BOS. Clinicians, patients, third-party payers, institutional review committees, other stakeholders or the courts should never view these recommendations as dictates. No guidelines and recommendations can take into account all of the often compelling, unique individual clinical circumstances. Therefore, no one charged with evaluating clinicians' actions should attempt to apply the recommendations from these guidelines by rote or in a blanket fashion.

Statements about the underlying values and preferences as well as the qualifying remarks accompanying each recommendation are integral parts and serve to facilitate more accurate interpretation. They should never be omitted when quoting or translating recommendations from these guidelines.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Meyer KC, Raghu G, Verleden GM, Corris PA, Aurora P, Wilson KC, Brozek J, Glanville AR, ISHLT/ATS/ERS BOS Task Force Committee. An international ISHLT/ATS/ERS clinical practice guideline: diagnosis and management of bronchiolitis obliterans syndrome. Eur Respir J. 2014 Dec;44(6):1479-503. [180 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Dec

Guideline Developer(s)

American Thoracic Society - Medical Specialty Society

European Respiratory Society - Professional Association

International Society for Heart and Lung Transplantation - Professional Association

Source(s) of Funding

International Society for Heart and Lung Transplantation (ISHLT)/American Thoracic Society (ATS)/European Respiratory Society (ERS)

Guideline Committee

ISHLT/ATS/ERS BOS Task Force Committee

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Financial Disclosures/Conflicts of Interest

All members of the committee disclosed potential conflicts of interest, which were vetted according to the policies of the International Society for Heart and Lung Transplantation (ISHLT), American Thoracic Society (ATS) and European Respiratory Society (ERS). Disclosures can be found alongside the online version of this article at erj.ersjournals.com.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the European Respiratory Journal Web site.

Availability of Companion Documents

The following are available:

- Diagnosis and management of bronchiolitis obliterans syndrome: an international ISHLT/ATS/ERS clinical practice guideline. Online supplement. 44 p. Electronic copies: Available from the European Respiratory Journal Web site.
- An international ISHLT/ATS/ERS clinical practice guideline: diagnosis and management of bronchiolitis obliterans syndrome. Evidence tables. 45 p. Electronic copies: Available from the European Respiratory Journal Web site.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on July 3, 2015. The information was verified by the guideline developer on July 28, 2015.

Copyright Statement

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